Amendments to the Drawings:

The attached sheets of drawings include changes to Figures 1A 1B and 4. These sheets, which includes Figs. 1A 1B and 4 replace 1A, 1B, and 4 the original sheets including Figures 1A, 1B and 4.
Attachment: Replacement Sheets

REMARKS/ARGUMENTS

Amendments

1. The abstract, specification and the drawings have been amended as directed by the Examiner. Specifically, the abstract has been amended to replace the word comprising, the specification has been amended to include the number 50 as the designated numeral for the expelling material, and the drawings have been amended to show where this material is located. These amendments add no new matter to the specification and acceptance of these amendments is respectfully requested.

2. All of the claims of the application have been amended to include the limitation that the present invention is directed to a means for delivering oral medications. Support for this amendment is found in the title of the application as well as paragraph 25 of the application as filed. In addition to this amendment:

3. Claim 1 of the application has been amended to include the limitations that the ampule is a puncturable ampule that contains a liquid oral medication and that the system contains a calibrated puncturing device that enables the ampule to be punctured. Support for these amendments is found throughout the application including the title and particularly in paragraphs 9, 21, and 23, 24 of the application as filed. These amendments add no new matter to the specification and acceptance of these amendments is respectfully requested.

4. Claim 2 has been amended to include the limitation that the ampule is a laterally squeezable ampule with a laterally squeezable propellant chamber. Support for these amendments is found on page 21 when viewed in conjunction with figures 1A, 1B and 4 of the application as filed. Because this paragraph teaches that the handle 34 prevents excess pressure from being applied to the ampule when the ampule is being punctured, and the expelling of the material of the device is obtained by squeezing the device. This paragraph teaches that the ampule is laterally compressible and not longitudinally compressible. These amendments add no new matter to the specification and acceptance of these amendments is respectfully requested.

5. Claims 4 and 5 of the application have been canceled and the subject matter previously set forth in these claims has been incorporated into claim 1.

6. Claim 6 has been amended to depend from claim 3 instead of claim 5 in as much as claim 5 has been canceled.

7. Claim 9 has been amended to include the limitations that the medicine while being stored in a powdered form is delivered in a liquid form, and that the membrane which separates the powdered medication in the first chamber from the reconstituting liquid in the second chamber is a pressure sensitive breakable membrane that is configured to be broken when a preselected quantity of pressure is applied to the membrane thus allowing the powder to be suspended within the reconstituting liquid. Claim 9 has also been amended to include a calibrated puncturing device which is configured to produce a hole of a calibrated size within the ampule. Support for these amendments is found in paragraphs 22-25 of the application as filed,

these amendments add no new matter to the specification and acceptance of these amendments is respectfully requested.

8. Claims 12 and 13 of the application have been canceled from the application as filed and the limitations which were included in this application have been included in amended claim 9.

9. Applicant respectfully requests acceptance of these amendments and allowance of these claims in view of the previously described amendment and the following remarks.

Standards for Patentability

10. "An applicant for a patent is entitled to the patent unless the application fails to meet the requirements established by law. It is the Commissioner's duty (acting through the examining officials) to determine that all requirements of the Patent Act are met. The burden is on the Commissioner to establish that the applicant is not entitled under the law to a patent .... In rejecting an application, factual determinations by the PTO must be based on a preponderance of the evidence, and legal conclusions must be correct." *In re Oetiker,* 977 F.2d 1443, 1449, 24 USPQ2d 1443, 1447,24 USPQ2d at 1447 (Fed. Cir. 1992) (Judge Plager concurring).

11. "The precise language of 35 USC 102 that 'a person shall be entitled to a patent unless,' concerning novelty and unobviousness, clearly places a burden of proof on the Patent Office which requires it to produce the factual basis for its rejection of an application under sections 102 and 103." *In re Warner,* 379 F.2d 1011, 1016, 154 USPQ 173 (CCPA 1967), cert. denied, 389 U.S. 1057, reh'g denied, 390 U.S. 1000 (1968).

Claim Rejections - 35 USC § 102

12. The Examiner rejected claims 1-7 and 9-15 under §102(b) as being anticipated by Freeberg et al., as well as by Mukasa et al. Applicant respectfully disagrees.

13. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d. 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as contained in the . . . claim." *Richardson v. Suzuki Motor Co.,* 828 F.2d 1226,1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). MPEP § 2131.

14. The claims of the application have been amended to include a variety of features that are not present in the Freeberg et. al. or the Mukasa references.

15. As a preliminary matter none of the references which have been cited by the Examiner are directed to a delivery device for providing an oral medication. The references which have been cited by the Examiner include devices for intramuscular and intravenous injections as well as devices for performing dental work. None of these references are directed towards oral medications or oral medication delivery systems as the amended claims of the present invention require.

16. Claim 1 and all of its associated dependent claims now require the presence of a puncturable, laterally compressible ampule having a closed body with a pre-selected quantity of a selected liquid medication therein. The ampule being configured to hold a premeasured quantity of selected medication, and to dispense this quantity of medication through an opening in the ampule after the opening is formed within the ampule and a designated quantity of pressure is applied to the ampule. Neither the Freeberg or the Mukasa references teach a device with these features. Both the Freeberg and the Mukasa describe a device that is longitudinally compressible.

17. The Freeberg device teaches a hypodermic needle that contains a powdered material that can be suspended in a liquid material to prepare it for injection through the needle. The hypodermic needle of the Freeberg device is not the closed, compressible and puncturable ampule which is claimed in the present invention. The hypodermic needle of the Freeberg invention is a metal needle that is connected to a glass or ceramic cylinder with an open top end into which a plunger is inserted. It is the movement of the plunger within the cylinder which causes material to be expelled out of the device through a preexisting hole in the cylinder which

is communicatingly connected to the hypodermic needle of that invention. This is not what the present invention claims or teaches.

18. The Mukasa reference teaches the presence of a capsule of dental additives which are kept in separate containers and which are configured for mixing just prior to use. The Mukasa reference teaches the use and inclusion of a plunger which is placed in the rear of the device and which pushes through the device to mix and deliver various items out of this container. This is not what the present invention is or what is claimed in the claims of application. The Mukasa device is not laterally compressible or squeezable as the device in the present invention requires.

19. The present invention claims and teaches the presence of an ampule having a closed body made of a compressible material which can be punctured by a calibrated puncturing device, and which is compressible from the sides. Neither the Freeberg or the Mukasa reference teach or include these features. Both the Freeberg and the Mukasa references teach the presence of syringe type delivery devices wherein a piston is moved through a chamber of the device to mix and express material out of the device. Furthermore, neither of these devices teach the presence of a calibrated puncturing device that is configured to puncture the ampule and create an opening of a desired size within the ampule.

Claim Rejections - 35 USC § 103

20. The Examiner rejected claims 6, 8, 14 and 16 under §103(a) as being unpatentable (obvious) over the combination of Freeberg in view of Schmid, as well the combination of Mukasa in view of Discko.

21. "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves of in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to

combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on the applicant's disclosure. *In re Vaeck,* 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)." MPEP § 706.02(j).

22. The law regarding obviousness is clear--any modification of the prior art must be suggested or motivated by the prior art.

> 'Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined only if there is some suggestion or incentive to do so.' [citation omitted] Although couched in terms of combined teachings found in the prior art, the same inquiry must be carried out in the context of a purported obvious "modification" of the prior art. The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.

In re Fitch, 972 F.2d 1260, 23 USPQ2d 1780, 1783-4 (Fed.Cir. 1992), (in part quoting from *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984)).

23. There is no suggestion in any of the references individually nor in combination that teach doing what the present inventor has done. Furthermore, the combinations which have been assembled by the Examiner fail to include each and every feature that has been set forth in the prior art. The combinations which have been made by the Examiner do not teach the presence of an oral pre-dosed medicine delivery device that includes a laterally compressible ample which is packaged in a container with an ampule piercing device that is configured to produce a hole of a desired size within the ampule.

24. These elements are a part of claims 6, 8, 14 and 16 as they are currently amended. The combination of references that have been assembled by the Examiner fail to the presence of a closed ampule that is laterally compressible and that is made of a material that is puncturable so as to produce an opening of a calibrated size for delivery of measured quantities of a liquid medication. All of the devices that have been cited by the Examiner include a sliding plunger that extends through the rear portion of the device and which is utilized to push material out of a preformed opening in that part of the device. None of these devices teach a device that is laterally compressible and puncturable and where the device for puncturing the ampule is a portion of the storage container in which the device is held.

25. Furthermore, none of the devices that have been cited by the Examiner include a puncturing device that is a portion of the container in which the ampule is held nor do any of these references teach the desirability of modifying the device to arrive at such a device.

26. The device taught in the Discko device is a tray for holding cartridges of dental

equipment which are later used within a tool. The Discko device does not teach or describe any ampule penetrating device much less a calibrated ampule penetrating device that is integrated into the tray itself. Similarly, neither the Schmid, Freeberg or Mukasa references teach the presence of this feature. There is no suggestion or motivation in the references themselves to do what the applicant has done.

27. None of these references teach the inclusion of any such puncturing device that can be connected to the bottom portions of the generally rectangular container. Nevertheless, the Examiner has argued that such a modification would have been an obvious one. Applicant respectfully disagrees and asserts that the Examiner has improperly used hindsight reasoning to arrive at this combination.

28 The Examiner is required by statute to prove motivation to modify the prior art. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"), see also *In re Rouffet*, 149 F.3d 1350, 1359 (Fed. Cir. 1998) ("the Board must identify specifically...the reasons one or ordinary skill in the art would have been motivated to select the references and combine them").

29. This objective evidence must be proved by motivation and must be credible.

> "The factual inquiry whether to combine references must be thorough and searching." It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with:
>
> - conclusory statements such as those here provided do not fulfill the agency's obligation
> - "Common knowledge and common sense," even if assumed to derive from the agency's expertise, do not substitute for authority where the law requires authority.
>
> *In re Lee*, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002).

30. The prior art must show reasonable expectations of success.

> "Both the suggestion and the expectation of success must be founded in the prior art, not in applicant's disclosure." *In re Dow Chemical Co. v. American Cyanamid Co.*, 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988).
>
> "Obvious to try or to experiment is not sufficient." *Yamanouchi Pharmaceutical Co., Ltd. v. Marsam Pharmaceuticals, Inc.*, 231 F.3d 1339, 56 USPQ2d 1641 (Fed. Cir. 2000).

31. There is no teaching in the prior art references that have been assembled by the Examiner nor has there been any suggestion provided by the Examiner to modify the references in a way whereby a calibrated puncturing device is included in the bottom portion of a generally rectangular ampule container.

32. It is further submitted that when a suggestion or motivation to combine selected elements

of prior art references is not supplied by the prior art, the incentive to make such a combination can only come from improper hindsight reconstruction using the applicant's specification.

In re Fritch, 972 F.2d 1260, 23 USPT2d 1780, 1784 (Fed.Cir. 1992), (in part quoting from *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988)).

To draw on hindsight knowledge of the patented invention, when the prior art does not contain or suggest that knowledge, is to use the invention as a template for its own reconstruction -- an illogical and inappropriate process by which to determine patentability. *W.L. Gore & Assoc. v. Garlock, Inc.* 721 F.2d 1132, 1138, 220 USPQ 303, 312-13 (Fed. Cir. 1983). The invention must be viewed not after the blueprint has been drawn by the inventor, but as it would have been perceived in the state of the art that existed at the time the invention was made. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985).

34. The Freeman and the Mukasa references are complete and functional without the need for modification. Absent the need for modification, the references could never lead one to make modifications to meet the claims. In such a case, the combining of items from various fields to attempt to arrive at the combination which has been claimed by the Applicant is improper hindsight.

35. In addition, as is described in letters attached to the present invention is not merely an obvious modification of the prior art, but is a new and useful device that meets the requirements for patent issuance.

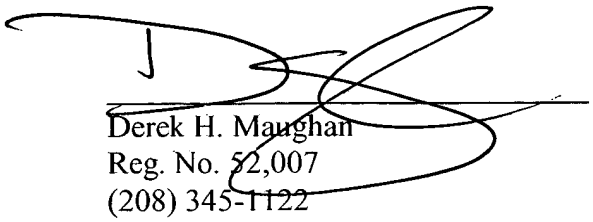
Conclusion

If the Examiner feels it would advance the application to allowance or final rejection, the Examiner is invited to telephone the undersigned at the number given below.

Reconsideration and allowance of the application as amended is respectfully requested.

DATED this 26th day of June 2006.

Very respectfully,



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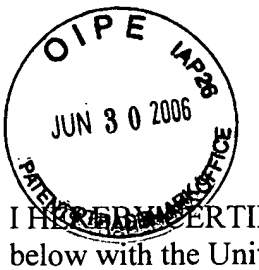

CERTIFICATE OF MAILING

I HEREBY CERTIFY that this correspondence is being deposited on the date below with the United States Postal Service as first class mail in an envelope addressed to:

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DATED: This 26th day of June 2004.

Brandy L. Potter

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